II. REMARKS

Introductory Comments

Claims 20-23 and 56-79 were examined in the Office Action under reply and stand variously rejected under (1) 35 U.S.C. § 112, second paragraph; and (2) 35 U.S.C. §112, first paragraph. These grounds of rejection are believed to be overcome by this response and are otherwise traversed for reasons discussed in detail below.

Applicants note with appreciation the withdrawal of the previous rejections under 35 U.S.C. §102 and 35 U.S.C. §103.

Overview of the Above Amendments

Claim 20 has been amended to recite the invention with greater particularity. Specifically, claim 20 now specifies that the assay kit comprises an antibody "reactive with" an HCV glycoprotein having mannose-terminated glycosylation. Support for this recitation is implicit in original claim 20 as filed. In particular, in order to be able to detect the presence of the HCV glycoprotein using an antibody, the antibody **must** be reactive with that glycoprotein.

Claims 56-68 have been cancelled. Cancellation of these claims and amendment of claim 20 is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications containing the unamended claims.

Rejection under 35 U.S.C. §112, Second Paragraph

The Office rejected claims 20-23 and 56-79 under 35 U.S.C. §112, second paragraph, based on the recitation "binds to." The Office argues it is unclear "what specificity is envisioned" and it is unclear whether "the antibody is directed against the asialoglyco part, the amino acid residues or conformation of native protein." Office Action, page 3. Applicants have amended claim 20 to eliminate the recitation "binds to." Moreover, it is unnecessary to specify which portion of the HCV glycoprotein the antibodies present in the assay kits bind. Rather, the antibody in the assay kits need merely be "reactive" with the asialoglycoprotein, but need not be reactive with a specific

part of the protein. Thus, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

Rejection under 35 U.S.C. §112, First Paragraph

Claims 20-23 and 56-79 were rejected under 35 U.S.C. §112, first paragraph, as nonenabled. The Office states that "the specification, while being enabling for concept of using an antigen to make an antibody, does not reasonably provide enablement for making an antibody for the stated antigen." Office Action, page 3. However, applicants respectfully submit that the antibodies for use in the claimed assay kits are indeed enabled.

The test for enablement is "whether one skilled in the art could make or use the claimed invention from the disclosure in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988); *In re Wands*, 8 USPQ2d 1400 (Fed Cir. 1988). Thus, in order to satisfy the enablement requirement of §112, the specification need only set forth such information as is sufficient to allow one of ordinary skill in the art to make and use the invention. How such a teaching is accomplished, either by the use of illustrative examples or by broad terminology, is of no importance since a specification which teaches how to make and use the invention in terms which correspond in scope to the claims must be taken as complying with the first paragraph of §112 unless there is reason to doubt the objective truth of the statements relied upon therein for enabling support (*In re Marzocchi*, 169 USPQ 367 (CCPA 1971)). Moreover, the specification need not teach and preferably omits that which is known to those working in the field. *See, e.g., Loom Co. v. Higgins,* 105 U.S. 580, 585-86 (1882); *In re Wands,* 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) and *In re Gay,* 309 F.2d 769, 774 (CCPA 1962) pointing out that "not every last detail [of an invention need] be described [in a specification], else patent specifications would turn into production specification, which they were never intended to be."

Applicants submit that based on these tenets, they have indeed enabled the claimed invention. Applicants describe the expression of HCV asialoglycoproteins at page 9, line 24, to page 11, line 20, and in Example 1. The purification of the recombinantly produced asialoglycoproteins is described at page 11, line 21 to page 12, line 25, while Examples 3 and 4

provide detailed steps for purification of the asialoglycoproteins using lectin and further chromatographic purification. Applicants then provide a detailed description for preparing immunogenic compositions using the isolated and purified asialoglycoproteins at page 14, line 24, to page 15, line 28. The applicants have thus enabled the production of the antigen and compositions including the antigen for producing antibodies "reactive with" the antigen.

Moreover, the Federal Circuit has on several occasions acknowledged that making and testing antibodies for reactivity is utterly routine. See, e.g., *In re Wands* at 1404; and *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986). Both of these cases establish that production of antibodies and screening methods were well known well before the present application was filed. Accordingly, applicants submit that one of skill in the art could make and use the claimed invention from the disclosure in the patent coupled with information known in the art without undue experimentation. *United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988); *In re Wands*, 8 USPQ2d 1400 (Fed Cir. 1988).

Based on the foregoing, the Examiner is respectfully requested to withdraw the rejection for lack of enablement.

Claims 20-23 and 56-79 were also rejected under 35 U.S.C. §112, first paragraph "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action, page 4. The Office states "the specification contains no reference to physical properties or structure of the antibody nor does it teach antibodies binding to E1 or E2...Applicant may have contemplated the antibodies but did not convey in the specification that they were in fact in possession of the claimed antibodies." Office Action, pages 4-5, bridging paragraph. The Office argues the present case is not analogous to Example 16 provided in the Office's "Synopsis of Application of Written Description Guidelines." However, applicants continue to assert that the antibodies used in the claimed assay kits are indeed adequately described and that Example 16 is in fact **directly** relevant to this application.

A copy of Example 16 is provided for the Office's convenience. As in Example 16, the present application teaches the purification and isolation of the recited asialoglycoproteins. As in

Example 16, the specification contemplates but does not exemplify the antibodies. As stated in Example 16:

> The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE...It is well known that antibodies can be made against virtually any protein.
>
> * * *
>
> The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.
>
> * * *
>
> Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X.
>
> **Conclusion:** The disclosure meets the requirement under 35 USC first paragraph as providing an adequate written description of the claimed invention.

The Examiner's determination that Example 16 is inapplicable to the present claims is simply in error.

Example 16 above and the Guidelines on Written Description confirm the seminal rule that the specification need only describe in detail that which is new or not conventional. See, Guidelines on Written Description, page 275. In the instant case, a skilled artisan, reading the specification in view of the state of the art, would have recognized that applicants were in possession of the antibodies recited in the claims. See, for example, page 15, lines 2-4, explaining that immunogenic compositions including the HCV asialoglycoproteins, can be used to generate antibodies. Further, the fact that original claims 20-23 were directed to assay kits for detecting HCV asialoglycoproteins using antibodies confirms that applicants were indeed in possession of the claimed invention at the time the application was filed.

Based on the foregoing, applicants assert that the present application complies with the written description requirement of 35 U.S.C. §112, first paragraph and respectfully request withdrawal of this basis for rejection.

Finally, claims 20-23 and 56-79 were rejected as containing new matter. The Office asserts the recitation "does not bind to other HCV proteins" is not supported. Although applicants believe the previous claims to be adequately supported, this recitation is no longer present. Accordingly, the rejection no longer applies and withdrawal thereof is respectfully requested.

CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. §112. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Please direct all further communications in this application to:

Alisa Harbin, Esq.
Chiron Corporation
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097
Telephone: (510) 923-2708
Facsimile: (510) 655-3542.

Respectfully submitted,

Date: 10/7/04

By: _____
Roberta L. Robins
Registration No. 33,208

CHIRON CORPORATION
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097

Example 16: Antibodies

Specification: The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach in an example antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in the form of complementarity determining regions and the framework regions. The sequences of constant regions as well as the variable regions subgroups (framework regions) from a variety of species are known and published in the art. It is also well known that antibodies can be made against virtually any protein.

Claim: An isolated antibody capable of binding to antigen X.

Analysis:

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-

characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

The claim is directed to any antibody which is capable of binding to antigen X.

A search of the prior art indicates that antigen X is novel and unobvious.

Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X.

Conclusion: The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.